

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESale PRICE  
LITIGATION

MDL No. 1456  
Master File No.: 01-CV-12257-PBS  
(original S. D. Iowa No. 4:07-cv-00461-  
JAJ-CFB)

THIS DOCUMENT RELATES TO:  
*State of Iowa v. Abbott Laboratories, et al.*

Judge Patti B. Saris

**THE JOHNSON & JOHNSON DEFENDANTS' ANSWER AND AFFIRMATIVE  
DEFENSES TO THE STATE OF IOWA'S COMPLAINT**

Defendants Johnson & Johnson, Janssen L.P. (f/k/a Janssen Pharmaceutica Products, L.P.), Ortho-McNeil Pharmaceutical, Inc., Ortho Biotech Products, L.P., McNeil PPC, Inc., McNeil Consumer & Specialty Pharmaceuticals, ALZA Corporation, Centocor, Inc., and Ethicon, Inc., ("the J&J Defendants"), by and through their attorneys, hereby state as an Answer and Affirmative Defenses to the State of Iowa's Complaint, dated October 9, 2007, as follows:

**PRELIMINARY STATEMENT**

The State of Iowa's Complaint (the "Complaint") improperly refers to the J&J Defendants, other Defendants, and third parties on a collective basis, failing to plead with requisite particularity allegations against each individual J&J Defendant. This is insufficient to apprise each J&J Defendant of the allegations asserted against it. The J&J Defendants have nevertheless attempted to respond to Plaintiff's allegations to the extent possible.

To the extent the allegations in the Complaint refer to the knowledge, conduct or actions of other persons or entities, the J&J Defendants are generally without knowledge or information sufficient to form a belief as to the truth of those allegations. The J&J Defendants state that they are answering Plaintiff's allegations solely on behalf of themselves, even when Plaintiff's allegations refer to alleged conduct by the J&J Defendants and other persons or entities.

The Complaint also contains purported quotations from a number of sources. In answering allegations consisting of quotations, the J&J Defendants' failure to deny that the material quoted was contained in a document or was uttered by the person or entity quoted or the J&J Defendants' reference to the full document instead of the quote shall not constitute an admission that the substantive content of the quote or document is or is not true or that the material is relevant or admissible in this action.

The J&J Defendants deny each and every allegation contained in the Complaint and the exhibits thereto, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos or speculation contained in any particular averment or in the Complaint as a whole. In addition, the J&J Defendants specifically deny any allegations contained in headings, footnotes, or unnumbered paragraphs in the Complaint. For ease of reference, the J&J Defendants have included in this Answer and Affirmative Defenses certain captions used in the Complaint, but specifically deny any allegations contained in, or inferences that could be drawn from, those captions.

These comments and objections are incorporated, to the extent appropriate, into each unnumbered and numbered paragraph of this Answer.

**SPECIFIC RESPONSES**

1. The J&J Defendants admit that the State of Iowa (the “State”) seeks to bring this action as alleged in Paragraph 1 of the Complaint, but the J&J Defendants deny that there is any basis for the State to do so and deny that the State is entitled to any relief.

2. To the extent the allegations in Paragraph 2 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they “purposefully report false and inflated price information.” To the extent the allegations in Paragraph 2 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

3. Paragraphs 3 through 4. To the extent the allegations in Paragraphs 3-4 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they submit “false and inflated pricing information in order to ‘create a spread.’” The J&J Defendants further deny the characterization of “spread” in Paragraphs 3-4. To the extent the allegations in Paragraphs 3-4 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

4. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5.

5. To the extent the allegations in Paragraph 6 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that

they “purposefully manipulate a market that, by defendants’ own design, is extremely complicated and non-transparent.” To the extent the allegations in Paragraph 6 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

6. Paragraphs 7 through 8. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 7-8.

7. To the extent the allegations in Paragraph 9 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they engage in any “unlawful price reporting activity [that] infects all four [pricing] benchmarks and renders each of them false and inflated.” To the extent the allegations in Paragraph 9 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

8. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10, except that they admit that some of them, not including Johnson & Johnson, pay Medicaid rebates to Iowa and that such rebates lower the price Iowa Medicaid pays for the J&J Defendants’ prescription drugs. To the extent the allegations in Paragraph 10 or its footnote refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

9. To the extent the allegations in Paragraph 11 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they do not accurately report Best Prices. To the extent the allegations in Paragraph

11 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

10. To the extent the allegations in Paragraph 12 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they engage in “unlawful pricing schemes,” the “manipulation of the Medicaid program” or the “improper reporting of false and inflated pricing information” resulting in “overcharges . . . to the Iowa Medicaid Program.” To the extent the allegations in Paragraph 12 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

11. To the extent the allegations in Paragraph 13 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they engage in “wrongful practices” that have a “pernicious . . . effect on the public fisc.” To the extent the allegations in Paragraph 13 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

12. Paragraphs 14 through 15. The J&J Defendants admit that some of them, not including Johnson & Johnson, voluntarily participate in the Iowa Medicaid program, but deny that they have violated any State or Federal law. To the extent the allegations in Paragraphs 14-15 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 14-15 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied.

13. To the extent the allegations in Paragraph 16 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they “intentionally report false prices to the government.” To the extent the allegations in Paragraph 16 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

14. To the extent the allegations in Paragraph 17 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they engage in “fraudulent, unfair and deceptive practices.” To the extent the allegations in Paragraph 17 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

15. The J&J Defendants admit that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but deny any liability to Plaintiff with respect to any such NDCs. To the extent the allegations in Paragraph 18 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

16. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19. To the extent the allegations in Paragraph 19 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

17. To the extent that the allegations in Paragraph 20 are directed at the J&J Defendants, the J&J Defendants deny them, except the J&J Defendants admit that some of them, not including Johnson & Johnson, manufacture and sell prescription drugs and participate in the Iowa Medicaid Program. To the extent the allegations in

Paragraph 20 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

18. The J&J Defendants admit that some of them, not including Johnson & Johnson, conduct business in the State of Iowa.

19. Paragraphs 22 through 39. The allegations in Paragraphs 22-39 are directed to other Defendants and require no response from the J&J Defendants. To the extent a response is deemed to be required, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 22-39.

20. Paragraph 40 (a)-(h). With respect to the allegations in Paragraphs 40 (a), the J&J Defendants admit that Johnson & Johnson is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, NJ, 08933. With respect to the allegations in Paragraphs 40 (b), the J&J Defendants admit that Janssen L.P. (f/k/a Janssen Pharmaceutica Products, L.P.), is a New Jersey limited partnership with a principal place of business located at 1125 Trenton-Harbourton Road, Titusville, NJ 08560, and that it manufactures and sells pharmaceuticals. With respect to the allegations in Paragraphs 40 (c), the J&J Defendants admit that Ortho-McNeil Pharmaceutical, Inc., is a Delaware corporation with a principal place of business located at 1000 U.S. Route 202 South, Raritan, NJ 08869, and that it manufactures and sells pharmaceuticals. With respect to the allegations in Paragraphs 40 (d), the J&J Defendants admit that Ortho Biotech Products, L.P. is a New Jersey limited partnership with a principal place of business located at 700 U.S. Highway 202, Raritan, NJ 08869, and that it manufactures and sells pharmaceuticals.

With respect to the allegations in Paragraphs 40 (e), the J&J Defendants admit that McNeil-PPC, Inc., is a New Jersey corporation with a principal place of business located at 7050 Camp Hill Road, Fort Washington, PA 19034, and that it manufactures and sells pharmaceuticals, and that McNeil Consumer & Specialty Pharmaceuticals is a division of McNeil-PPC. With respect to the allegations in Paragraphs 40(f), the J&J Defendants admit that ALZA Corporation is a Delaware corporation with a principal place of business located at 1900 Charleston Road, Mountain View, CA, that ALZA manufactures pharmaceuticals, and that, for a time, ALZA marketed pharmaceuticals. With respect to the allegations in Paragraphs 40(g), the J&J Defendants admit that Centocor, Inc., is a Pennsylvania corporation with a principal place of business located at 244 Great Valley Parkway, Malvern, PA, and that it manufactures and sells pharmaceuticals. With respect to the allegations in Paragraphs 40(h), the J&J Defendants admit that Ethicon, Inc. is a New Jersey corporation with a principal place of business located at Route 22 West, Somerville, NJ, and that it manufactures and sells surgical products. The J&J Defendants otherwise deny the allegations in Paragraph 40(a)-(h) of the Complaint.

21. Paragraphs 42 through 58. The allegations in Paragraphs 28-58 are directed to other Defendants and require no response from the J&J Defendants. To the extent a response is deemed to be required, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 28-58.

22. The J&J Defendants admit that the State seeks to bring this action as alleged in Paragraph 59, but the J&J Defendants deny there is any basis for the State to do so and denies that the State is entitled to any relief.



23. Paragraphs 60 through 61. Paragraphs 60-61 state legal conclusions as to which no response is required. To the extent a response is deemed to be required, the J&J Defendants deny the allegations in Paragraphs 60-61, and note that this captioned matter has been transferred to this Court by the Judicial Panel on Multi District Litigation, pursuant to 28 U.S.C. § 1407.

24. With respect to the allegations in Paragraph 62, the J&J Defendants admit that Medicaid was established by Title XIX of the Social Security Act. The J&J Defendants further state that the provisions of Title XIX speak for themselves, and any characterizations thereof are denied.

25. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 63, except the J&J Defendants admit that state participation in Medicaid is voluntary and that state Medicaid plans must be approved by the federal government. To the extent the allegations in Paragraph 63 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

26. Paragraphs 64 through 65. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 64-65. To the extent the allegations in Paragraphs 64-65 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

27. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 66, except admit that national drug codes are assigned to prescription drugs.

28. To the extent the allegations in Paragraph 67 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied. The J&J Defendants otherwise deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 67.

29. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68. To the extent the allegations in Paragraph 68 refer to an OIG report, the report speaks for itself, and any characterizations thereof are denied.

30. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69. To the extent the allegations in Paragraph 69 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

31. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70.

32. Paragraphs 71 through 72. To the extent the allegations in Paragraphs 71-72 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants further state that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 71-72 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

33. Paragraphs 73 through 80. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 73-80 or their subsections. To the extent the allegations in Paragraphs 73-80 or their subsections refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

34. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 81, except that they admit that pricing compendia such as First DataBank and Medi-Span publish AWP's and FUL's, and deny that the J&J Defendants have any control over such prices.

35. To the extent the allegations in Paragraph 82 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they "purposefully and fraudulently conceal" the "true prices" of their drugs by "claiming they are proprietary trade secrets." To the extent the allegations in Paragraph 82 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

36. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 83.

37. To the extent the allegations in Paragraph 84 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they "fraudulently misrepresent" their true prices or that they report "false and inflated prices." To the extent the allegations in Paragraph 84 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

38. To the extent the allegations in Paragraph 85 are directed at the J&J Defendants, the J&J Defendants deny them, except that the J&J Defendants admit that Exhibit A purports to identify total expenditures by Defendant. The J&J Defendants specifically deny any “unfair practices, deception, and fraud.” To the extent the allegations in Paragraph 85 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

39. To the extent the allegations in Paragraph 86 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny conducting any “fraudulent practices.” To the extent the allegations in Paragraph 86 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

40. Paragraphs 87 through 89. To the extent the allegations in Paragraphs 87-89 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they report “false and inflated” “WACs or WAC equivalents.” To the extent the allegations in Paragraphs 87-89 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

41. Paragraphs 90 through 92. To the extent the allegations in Paragraphs 90-92 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants further state that these allegations wrongly assume that discounts, chargebacks and other price concessions are supposed to be included in prices published by industry compendia. To the extent the allegations in Paragraphs 90-92 are directed at

parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

42. Paragraphs 93 through 98. To the extent the allegations in Paragraphs 93-98 are directed at the J&J Defendants, the J&J Defendants deny them, except the J&J Defendants admit that some of them, not including Johnson & Johnson, have provided the list price of their drugs to certain industry pricing compendia and that publishers apply their own markups to the list prices. The J&J Defendants specifically deny that they “either report[s] or caused to be reported false and inflated AWP,” “false WAC or WAC equivalents,” or that the J&J Defendants “alone control the false and inflated AWP that are published for their drugs.” The J&J Defendants further state that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 93-98 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

43. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 99.

44. To the extent the allegations in Paragraph 100 are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraph 100 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

45. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraph 101 or the exhibit referenced therein are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

46. Paragraphs 102 through 108. The allegations in Paragraphs 102-108 require no response from the J&J Defendants on the grounds that Exhibit B does not name any the J&J Defendants drugs subject to the FUL. To the extent the allegations in Paragraphs 102-108 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

47. The allegations in Paragraph 109 require no response from the J&J Defendants on the grounds that the Iowa SMAC claims have been dismissed by the Court.

48. Paragraphs 110 through 128. To the extent the allegations in Paragraphs 110-128 are directed at the J&J Defendants, the J&J Defendants deny them, except the J&J Defendants admit that some of them, not including Johnson & Johnson, have executed a rebate agreement with HHS. The J&J Defendants further state that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to the J&J Defendants. In any event, the rebate agreement speaks for itself, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 110-128 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth. To the extent the

allegations in Paragraphs 110-128 refer to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

49. Paragraphs 129 through 132. To the extent the allegations in Paragraphs 129-132 are directed at the J&J Defendants, the J&J Defendants deny them, and further state that the Court has dismissed all Medicaid rebate-related allegations in the Complaint as to the J&J Defendants. To the extent the allegations in Paragraphs 129-132 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 129-132 refer to statutes, regulations or reports, those sources speak for themselves, and any characterizations thereof are denied.

50. To the extent the allegations in Paragraph 133 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they have participated in any “pricing scheme . . . by exacerbating the complexities of the . . . drug market.” To the extent the allegations in Paragraph 133 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

51. To the extent the allegations in Paragraph 134 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they “purposefully conceal their true prices.” To the extent the allegations in Paragraph 134 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 134 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

52. To the extent the allegations in Paragraph 135 are directed at the J&J Defendants, they are denied. To the extent the allegations in Paragraph 135 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

53. To the extent the allegations in Paragraph 136 are directed at the J&J Defendants, they are denied, except the J&J Defendants admit that certain of their contracts are subject to confidentiality agreements and that some of them, not including Johnson & Johnson, offer discounts to certain customers. To the extent the allegations in Paragraph 136 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

54. To the extent the allegations in Paragraph 137 are directed at the J&J Defendants, the J&J Defendants deny them. the J&J Defendants specifically deny that they “obscure the true prices for their drugs with their policy of treating different classes of trade differently.” To the extent the allegations in Paragraph 137 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

55. Paragraphs 138 through 139. To the extent the allegations in Paragraphs 138-139 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they “maintain two sets of pricing records: one with [] inflated prices and another with [] actual prices.” To the extent the allegations in Paragraphs 138-139 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 138-139 refer to the transcript of a



congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

56. Paragraphs 140 through 141. To the extent the allegations in Paragraphs 140-141 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they “hide their real drugs prices by secretly providing free drugs and phony grants” or that they conceals their true prices “to create spreads between actual cost and reimbursement amounts . . . to influence market share.” To the extent the allegations in Paragraphs 140-141 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

57. To the extent the allegations in Paragraph 142 are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraph 142 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

58. To the extent the allegations in Paragraph 143 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants further state that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraph 143 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

59. Paragraphs 144 through 145. To the extent the allegations in Paragraphs 144-145 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they have engaged in any “unlawful and undisclosed manipulation of the price reporting system” or caused the “publication of a false WAC,” AWP, or FUL. To the extent the allegations in Paragraphs 144-145 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

60. To the extent the allegations in Paragraph 146 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they have “caus[ed] false prices to be published.” To the extent the allegations in Paragraph 146 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

61. To the extent the allegations in Paragraph 147 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they “submit false and inflated wholesale price information in order to create a spread.” The J&J Defendants further deny the characterization of “spread” in Paragraph 147. To the extent the allegations in Paragraph 147 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

62. To the extent the allegations in Paragraph 148 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they have “corrupted the market for prescription drugs” or have “deliberately sought to create a powerful financial incentive for providers to prescribe drugs based primarily

on the spread.” The J&J Defendants further deny the characterization of “spread” in Paragraph 148. To the extent the allegations in Paragraph 148 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

63. Paragraphs 149 through 150. To the extent the allegations in Paragraphs 149-150 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they “market their products based on the spread between reimbursement (based on AWP, WAC, or a WAC equivalent) and actual acquisition cost” or that they “compete on reimbursement and profit rather than cost.” To the extent the allegations in Paragraphs 149-150 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

64. Paragraphs 151 through 152. To the extent the allegations in Paragraphs 151-152 are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraphs 151-152 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 151-152 refer to the transcript of a congressional hearing, the transcript speaks for itself, and any characterizations thereof are denied.

65. Paragraphs 153 through 154. To the extent the allegations in Paragraphs 153-154 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they have “intentionally manipul[ed] the nation’s drug reimbursement system . . . with false and inflated prices.” To the extent the

allegations in Paragraphs 153-154 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

66. Paragraphs 155 through 157. To the extent the allegations in Paragraphs 155-157 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they report “reimbursement prices . . . to the publishing compendia” or that they engage in “purposeful AWP manipulation.” The J&J Defendants further state that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices. To the extent the allegations in Paragraphs 155-157 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 155-157 refer to HHS OIG reports, the reports speak for themselves, and any characterizations thereof are denied.

67. To the extent the allegations in Paragraph 158 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they report “price information that . . . does not comply with the HHS OIG’s guidelines” by not accounting for various types of discounts. To the extent the allegations in Paragraph 158 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

68. Paragraphs 159 through 165. The J&J Defendants deny knowledge or information to form a belief as to the truth of the allegations in Paragraphs 159-165, except the J&J Defendants admit some of them, not including Johnson & Johnson, participate in the Federal Medicaid Rebate Program through which Iowa Medicaid is obligated to reimburse providers for the J&J Defendants' drugs. The J&J Defendants further state that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual average of wholesale prices or have an expected relationship to such an average. To the extent the allegations in Paragraphs 159-165 refer to judicial opinions, those sources speak for themselves, and any characterizations thereof are denied.

69. To the extent the allegations in Paragraph 166 are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraph 166 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

70. Paragraphs 167 through 171. To the extent that the allegations in Paragraphs 167-171 are directed at the J&J Defendants, the J&J Defendants deny them, except the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegation that the "Iowa Medicaid Program spent over \$1.6 billion for defendants' drugs between 1992 and 2005 alone." The J&J Defendants specifically deny that they "knowingly interfered with Iowa's ability to reimburse providers at EAC." To the extent the allegations in Paragraphs 167-171 are directed at parties other than the J&J

Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

71. Paragraphs 172 through 177. With respect to the allegations in Paragraphs 172-177, the J&J Defendants admit that Exhibit B to the Complaint purports to identify the prescription drugs at issue in this matter, but deny the accuracy of the data listed therein. To the extent the remaining allegations in Paragraphs 172-177 or Exhibit B are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants specifically deny that they “routinely submitted false prices” to pricing compendia. The J&J Defendants further deny the characterization of “spread” in Paragraphs 172-177 and Exhibit B. To the extent the allegations in Paragraphs 172-177 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

72. To the extent the allegations in Paragraph 178 are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraph 178 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

73. To the extent the allegations in Paragraph 179 are directed at the J&J Defendants, the J&J Defendants deny them, except the J&J Defendants admit that some of them, not including Johnson & Johnson, sometimes provide contracted discounts with some purchasers. To the extent the allegations in Paragraph 179 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

74. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 180.

75. Paragraphs 181 through 210. The allegations in Paragraphs 181-210 are directed to other Defendants and require no response from the J&J Defendants. To the extent Paragraph 585 references the J&J Defendants, the allegations in that paragraph are denied. To the extent a response is deemed to be required, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 181-210.

76. To the extent the allegations in Paragraph 211 are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraph 211 or the document referenced therein are directed at the “Amgen Group,” the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

77. To the extent the allegations in Paragraph 212 are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraph 212 or the document referenced therein are directed at the “Amgen Group,” the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

78. The J&J Defendants deny the allegations in Paragraph 213 because, upon information and belief, the “Amgen Group” did not have a pricing strategy for Aranesp. The J&J Defendants deny any characterizations or inferences from Plaintiff’s citations.

79. To the extent the allegations in Paragraph 214 are directed at the J&J Defendants, the J&J Defendants deny them, except to admit that the AWP for Procrit did not decrease once. To the extent the allegations in Paragraph 214 or the document referenced therein are directed at the “Amgen Group,” the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

80. Paragraphs 215 through 424. The allegations in Paragraphs 215-424 are directed to other Defendants and require no response from the J&J Defendants. To the extent Paragraph 585 references the J&J Defendants, the allegations in that paragraph are denied. To the extent a response is deemed to be required, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 215-424.

81. The J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 425 or the footnote or exhibit referenced therein.

82. The J&J Defendants deny the allegations in Paragraph 426.

83. The J&J Defendants deny the allegations in Paragraph 427.

84. The J&J Defendants deny the allegations in Paragraph 428.

85. The J&J Defendants deny the allegations in Paragraph 429.

86. The J&J Defendants deny the allegations in Paragraph 430.

87. The J&J Defendants deny the allegations in Paragraph 431.

88. The J&J Defendants deny the allegations in Paragraph 432, except admit that WAC and AWP, by definition, do not include discounts.

89. The J&J Defendants deny the allegations in Paragraph 433.



90. The J&J Defendants deny the allegations in Paragraph 434, except admit that WAC and AWP, by definition, do not include nominal prices.

91. Paragraphs 435 through 613. The allegations in Paragraphs 435-613 are directed to other Defendants and require no response from the J&J Defendants. To the extent Paragraph 585 references the J&J Defendants, the allegations in that paragraph are denied. To the extent a response is deemed to be required, the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 435-613.

92. Paragraphs 614 through 616. To the extent the allegations in Paragraphs 614-616 are directed at the J&J Defendants, the J&J Defendants deny them, except the J&J Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegation that Iowa's Medicaid program "spent over \$1.6 billion for defendants' drugs in state and federal dollars from 1992 through 2005 alone." The J&J Defendants specifically deny that they were involved in any "false price reporting scheme" or "misconduct," or that they have been "unjustly enriched." To the extent the allegations in Paragraphs 614-616 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

93. Paragraphs 617 through 632. To the extent the allegations in Paragraphs 617-632 are directed at the J&J Defendants, the J&J Defendants deny them. The J&J Defendants further state that for years, and at all times relevant to the Complaint, it has been common knowledge and universally understood, including by the State and/or its agents, that AWP does not, and is not intended to, reflect an actual

average of wholesale prices. To the extent the allegations in Paragraphs 617-632 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 630 refer to *The Pink Sheet*, that document speaks for itself, and any characterizations thereof are denied.

## **COUNT I**

### **VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)**

94. In response to Paragraph 633, The J&J Defendants repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 632.

95. Paragraphs 634 through 642. To the extent the allegations in Paragraphs 634-642 are directed at the J&J Defendants, the J&J Defendants state that the Court has dismissed the claim to which these allegations relate. To the extent that a response is still required, the J&J Defendants deny the allegations as to themselves. To the extent the allegations in Paragraphs 634-642 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

## **COUNT II**

### **BREACH OF CONTRACT**

96. In response to Paragraph 643, the J&J Defendants repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 642.

97. Paragraphs 644 through 651. To the extent the allegations in Paragraphs 644-651 are directed at the J&J Defendants, the J&J Defendants state that the Court has dismissed the claim to which these allegations relate. To the extent that a response is still required, the J&J Defendants deny the allegations as to themselves. To the extent the allegations in Paragraphs 644-651 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth.

### **COUNT III**

#### **IOWA CONSUMER FRAUD ACT (Iowa Code § 714.16)**

98. In response to Paragraph 652, the J&J Defendants repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 651.

99. To the extent the allegations in Paragraph 653 and the exhibits referenced therein are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraph 653 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraph 653 refers to statutes or regulations, those sources speak for themselves, and any characterizations thereof are denied.

100. Paragraphs 654 through 657. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto are directed at parties other than the J&J Defendants, the J&J Defendants

deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto refer to statutes, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 654-657 and the sub-parts thereto contain legal conclusions, no response is required.

#### **COUNT IV**

##### **FRAUD**

101. In response to Paragraph 658, the J&J Defendants repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 657.

102. Paragraphs 659 through 662. To the extent the allegations in Paragraphs 659-662 and the exhibits referenced therein are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraphs 659-662 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 659-662 refer to Iowa law, those sources speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraphs 659-662 contain legal conclusions, no response is required.

#### **COUNT VIII**

##### **UNJUST ENRICHMENT**

103. In response to Paragraph 663, the J&J Defendants repeat and incorporate as if fully set forth herein each and every response to the allegations in Paragraphs 1 through 662.

104. Paragraphs 664 through 666. To the extent the allegations in Paragraphs 664-666 are directed at the J&J Defendants, the J&J Defendants deny them. To the extent the allegations in Paragraphs 664-666 are directed at parties other than the J&J Defendants, the J&J Defendants deny knowledge or information sufficient to form a belief as to their truth. To the extent the allegations in Paragraphs 664-666 contain legal conclusions, no response is required.

105. Paragraphs 667 through 675. The J&J Defendants deny that the State is entitled to a judgment or any other relief as requested in the unnumbered “WHEREFORE” paragraph and Paragraphs 667-675 of the Complaint.

**WHEREFORE**, the J&J Defendants demand judgment dismissing the Complaint with prejudice, and awarding reasonable expenses and costs incurred herein, and for such further relief as the Court deems just and proper.

### **AFFIRMATIVE DEFENSES**

#### **First Affirmative Defense**

Plaintiff fails to state a claim against the J&J Defendants upon which relief may be granted.

#### **Second Affirmative Defense**

Plaintiff’s claims are barred, in whole or in part, because it did not rely on any alleged misrepresentations or fraud by the J&J Defendants. Plaintiff knew that providers could obtain the J&J Defendants drugs at prices below AWP prior to the relevant time period stated in the Complaint.

**Third Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the political question doctrine and by the separation of powers doctrine.

**Fourth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the filed rate doctrine.

**Fifth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the state action doctrine.

**Sixth Affirmative Defense**

To the extent Plaintiff obtains recovery in any other case predicated on the same factual allegations, Plaintiff is barred from seeking recovery against the J&J Defendants based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

**Seventh Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by the J&J Defendants in judicial, legislative, or administrative proceedings of any kind or at any level of government.

**Eighth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff has released, settled, entered into an accord and satisfaction or otherwise compromised Plaintiff's claims.

**Ninth Affirmative Defense**

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, and the Prescription Drug, Improvement and Modernization Act of 2003, including all amendments to the same and all regulations promulgated thereunder.

**Tenth Affirmative Defense**

Plaintiff's claims against the J&J Defendants are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel, and waiver.

**Eleventh Affirmative Defense**

Plaintiff fails to state with particularity facts to support claims of fraudulent conduct, fraudulent concealment and the multi-source allegations against the J&J Defendants contained in the Complaint.

**Twelfth Affirmative Defense**

Any and all actions taken by the J&J Defendants with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

**Thirteenth Affirmative Defense**

The J&J Defendants' statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiff.

**Fourteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a consumer within the meaning of the Iowa Consumer Fraud Act.

**Fifteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff is not a person within the meaning of the Iowa Consumer Fraud Act.

**Sixteenth Affirmative Defense**

Some or all of Plaintiff's claims against the J&J Defendants arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

**Seventeenth Affirmative Defense**

The J&J Defendants deny that Plaintiff has a valid consumer protection claim against the J&J Defendants under the Iowa Consumer Fraud Act. However, if such claim is found to exist, the J&J Defendants plead all available defenses under the Act.

**Eighteenth Affirmative Defense**

To the extent that Plaintiff attempts to seek equitable relief against the J&J Defendants, Plaintiff is not entitled to such relief because Plaintiff has an adequate remedy at law.

**Nineteenth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint.



**Twentieth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by the J&J Defendants after the filing of the Complaint.

**Twenty-First Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, because the damages alleged are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

**Twenty-Second Affirmative Defense**

Plaintiff's claims against the J&J Defendants are barred, in whole or in part, due to its failure to join indispensable parties.

**Twenty-Third Affirmative Defense**

Plaintiff's claims against the J&J Defendants are barred, in whole or in part, because Plaintiff has not suffered damages as a result of the matters alleged in the Complaint.

**Twenty-Fourth Affirmative Defense**

Plaintiff's claims are barred, in whole or in part, (1) because Plaintiff failed to mitigate damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to the J&J Defendants; (2) because Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; and (3) because damages are speculative and remote and because of the impossibility of ascertaining and allocating alleged damages.

**Twenty-Fifth Affirmative Defense**

The J&J Defendants are entitled to a set-off, should any damages be awarded against them, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

**Twenty-Sixth Affirmative Defense**

Plaintiff's claims against the J&J Defendants are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Iowa Constitution.

**Twenty-Seventh Affirmative Defense**

Plaintiff's claims against the J&J Defendants are preempted by the Commerce Clause and/or the dormant Commerce Clause of the United States Constitution.

**Twenty-Eighth Affirmative Defense**

Plaintiff's claims against the J&J Defendants are barred, in whole or in part, because they violate the J&J Defendants' rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Iowa Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

**Twenty-Ninth Affirmative Defense**

Plaintiff's claims against the J&J Defendants are barred because Plaintiff and/or its agents knew and were aware that AWP was not an actual average of wholesale prices or the actual acquisition cost of pharmaceuticals. Legal and equitable principles preclude this action for damages and injunctive relief.

**Thirtieth Affirmative Defense**

The claims alleged herein, based on the facts alleged, are barred in whole or in part by Plaintiff's own negligence or gross negligence and the doctrines of comparative and/or contributory negligence. Among other things, the claims disregard Iowa's obligations under federal law.

**Thirty-First Affirmative Defense**

Plaintiff's prayers for relief in the form of restitution are barred, in whole or in part, because the J&J Defendants did not retain any money belonging to Plaintiff as a result of any alleged overpayments.

**Thirty-Second Affirmative Defense**

Plaintiff has failed to plead with particularity allegations of fraud by the J&J Defendants contained in the Complaint.

**Thirty-Third Affirmative Defense**

Plaintiff's claims for fraud and fraudulent concealment are barred because the Plaintiff cannot predicate a claim for fraud on reliance by a third party.

**Thirty-Fourth Affirmative Defense**

Plaintiff's claims against the J&J Defendants are barred because Plaintiff lacks standing or capacity to bring some or all of the claims asserted against the J&J Defendants under Iowa law.

**Thirty-Fifth Affirmative Defense**

Plaintiff's claims against the J&J Defendants are barred in whole or in part by the doctrine of voluntary payment.

**Thirty-Sixth Affirmative Defense**

Plaintiff's claims against the J&J Defendants for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

**Thirty-Seventh Affirmative Defense**

Plaintiff's claims against the J&J Defendants for unjust enrichment are barred because the Complaint does not allege that Defendants received any payment or property from the Plaintiff.

**Thirty-Eighth Affirmative Defense**

Plaintiff's claims against the J&J Defendants for injunctive relief against the J&J Defendants are barred by the doctrines of *in pari delicto* and/or unclean hands.

**Thirty-Ninth Affirmative Defense**

Plaintiff's claims against the J&J Defendants are misjoined with Plaintiff's claims against other Defendants and must be severed.

**Fortieth Affirmative Defense**

Any damages recovered by the Plaintiff must be limited by any applicable statutory ceiling on recoverable damages.

**Forty-First Affirmative Defense**

To the extent punitive damages are sought, Plaintiff's punitive damages claims against the J&J Defendants (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against the J&J Defendants; (3) cannot be sustained because the laws regarding the standards for determining liability for, and the amount of, punitive damages fail to give the J&J Defendants prior notice of the conduct for which punitive damages

may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of the J&J Defendants' due process rights guaranteed by the Fifth and the Fourteenth Amendments to the United States Constitution; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate the J&J Defendants' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and be improper under the Iowa Constitution and Iowa common law.

**Forty-Second Affirmative Defense**

Plaintiff fails to allege facts or a cause of action against the J&J Defendants sufficient to support a claim for prejudgment interest or any other relief.

**Forty-Third Affirmative Defense**

Plaintiff has not suffered, and will not suffer, any injuries to a legally protected or cognizable interest by reason of the conduct of the J&J Defendants as alleged in the Complaint.

**Forty-Fourth Affirmative Defense**

Plaintiff's claims against the J&J Defendants are barred because the J&J Defendants have complied with all applicable regulations of the federal and state governments.

**Forty-Fifth Affirmative Defense**

Plaintiff's claims against the J&J Defendants are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of intervening or superseding conduct of third parties.

**Forty-Sixth Affirmative Defense**

Plaintiff's claims against the J&J Defendants are barred, in whole or in part, because the J&J Defendants did not make any false statements to the Plaintiff. As to any statement asserted against the J&J Defendants that Plaintiff alleges to be false or misleading, the J&J Defendants had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

**Forty-Seventh Affirmative Defense**

Plaintiff fails to allege facts or a cause of action sufficient to support a claim against the J&J Defendants for compensatory damages, attorneys' fees, enhanced damages, treble damages and/or legal fees or costs.

**Forty-Eighth Affirmative Defense**

The J&J Defendants adopt by reference any additional applicable defense pled by any other Defendant not otherwise pled herein.

**Forty-Ninth Affirmative Defense**

The J&J Defendants hereby give notice that they intend to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve their right to amend their Answer to assert such defense.

Respectfully submitted,

Dated: September 18, 2008

/s/ Andrew D. Schau  
\_\_\_\_\_  
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**CERTIFICATE OF SERVICE**

I certify that I caused a true and correct copy of the ANSWER AND AFFIRMATIVE DEFENSES OF THE J&J DEFENDANTS CORPORATION TO THE STATE OF IOWA'S COMPLAINT to be delivered to all counsel of record by sending a copy to LexisNexis File and Serve, on September 18, 2008, for posting and notification to all parties.

September 18, 2008

/s/ Andrew D. Schau